

## **RESPONSE**

### **A. Status of the Claims**

Claims 45-61 were pending at the time of the Action with claims 51-52 and 55-60 being withdrawn as directed to non-elected inventions. Claims 55-60 have been canceled as being directed to a non-elected invention. Claims 45-47 and 61 have been amended. No new matter was added by these amendments. Claims 45-54 and 61 are now pending.

### **B. The Claims Are Supported by Adequate Written Description in the Specification**

Claims 45-50, 53-54, and 61 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not adequately described in the specification. Specifically, the Action alleges that the genus of “fragments” is not adequately described and that the inventors were not in possession of the predicted immunogenic fragments because of the unpredictability of the immunogenicity of linear peptides (Action, p. 2-3). Applicants traverse this rejection.

This rejection is based on the Examiner’s misreading of the claims and mischaracterization of the teachings in the specification. The Action states that “the claims still recite an isolated hyperimmune serum-reactive antigen comprising an immunogenic fragment of SEQ ID NO:364 or comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO: 364.” (Action, p. 3). This is not the language of the claims under examination at the time of the Action. The language of claim 45 was: “A pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen comprising an amino acid sequence of SEQ ID NO: 364 or an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO:364.” Accordingly, the immunogenic fragments of SEQ ID NO: 364 were all described with reference to specifically recited sequences.

Furthermore, the Action's allegation that the specification only discloses peptides that are "predicted" to be immunogenic is incorrect. As explained in Applicants previous response, Table 1A on page 77 discloses *identified immunogenic regions and predicted immunogenic amino acids* of SEQ ID NO:364. In particular, the Examiner's attention is drawn to the fifth column from the left in Table 1A. In addition, Tables 2 and 4 provide the results verifying the immunogenicity of the fragments of SEQ ID NO: 364. Although Applicants disagree with the Examiner's assertion that the peptide sequences that are predicted to be immunogenic are not adequately supported in the specification, Applicant has amended current claims 45 and 61 to recite "an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364."

Finally, the Examiner's assertion that "immunogenic" refers to a "physical property" and not a function of a peptide is not supported with any factual evidence. The Examiner merely cites definitions of the term "property," which do not mention "immunogenic." If this position is based on the Examiner's personal knowledge, then Applicants request the Examiner provide an affidavit as required under 37 C.F.R. § 1.104(d)(2).

In view of the above, one skilled in the art would reasonably conclude that the inventor had possession of the currently claimed invention. Applicants, therefore, request the withdrawal of this rejection.

### **C. The Claims Are Enabled**

The Action rejects claims 45-50, 53- 54, and 61 under 35 U.S.C. § 112, first paragraph, for lack of enablement. Applicants traverse this rejection.

As discussed above, current claim 45 is directed to a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364.

The Examiner has indicated that such a claim is enabled (Action dated 12/13/06, para. bridging p. 9-10). Furthermore, the specific sequences recited in the claim contain amino acid sequences that were demonstrated to be immunogenic (*see e.g.*, Specification, Tables 2 and 4). The specification also provides teachings as to how hyperimmune serum-reactive antigens and fragments thereof may be prepared in pharmaceutical compositions (*see e.g.*, Specification, p. 45).

To be enabling within the meaning of 35 U.S.C. § 112, the application must contain a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. The present specification provides such a disclosure. The specification provides the complete structure of SEQ ID NO: 364, and the Examiner acknowledges that the specification provides guidance on how to make a hyperimmune serum-reactive antigen comprising SEQ ID NO: 364 (Action dated 12/13/06, p. 10). Based on the disclosure of SEQ ID NO: 364, a person of ordinary skill in the art can readily identify and make an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364. As discussed above, amino acids 399-417, 503-519, 544-563, 489-556 of SEQ ID NO:364 were demonstrated to be highly reactive with individual human sera (Specification, Example 4, and Table 2), and amino acids 386-458 or 458-624 of SEQ ID NO:364 contain sequences that were demonstrated to be highly reactive with individual human sera.

Furthermore, assessing whether an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364 was capable of eliciting an immune response would not require undue experimentation because it could be accomplished by routine screening using methods such as those described in Example 4 in the present specification (*see In re Wands*, 858

F.2d 731, 737 (Fed. Cir. 1988). It is further noted that claims can include non-operative embodiments as long as it does not require undue experimentation to determine which embodiments are operable (MPEP § 2164.08(b); “Training Materials for Examining Patent Applications with Respect to 35 U.S.C. § 112, first paragraph - Enablement Chemical/Biotechnical Applications” available online at <http://www.uspto.gov/web/offices/pac/dapp/1pecba.htm>). One of ordinary skill in the art could determine the operable embodiments of the current claims without undue experimentation using routine screening using methods such as those described in Example 4 in the present specification.

Applicants further note that the Federal Circuit has stated that testing for the full safety and effectiveness of a particular drug for human use is more properly left to the Food and Drug Administration (FDA). *In re Brana*, 51 F.3d 1560, 1567 (Fed. Cir. 1995). Moreover, there is nothing in the patent statute or any other statutes that gives the Patent Office the right or the duty to require an applicant to prove that compounds he is claiming, and which he has stated are useful for “pharmaceutical applications,” are safe, effective, and reliable for use with humans. *In re Krimmel*, 292 F.2d 948, 954 (C.C.P.A. 1961); *see also* MPEP § 2164.01(c)

In view of the above, the present specification contains a description sufficient to enable one skilled in the art to make and use the claimed invention without unduly extensive experimentation. Applicants, therefore, respectfully request the withdrawal of the rejection.

#### **D. The Claims Are Novel Over Telford**

The Action rejects claims 45-49 and 53-54 under 35 U.S.C. § 102(b) as being anticipated by Telford *et al.* Accession No. ABP28545 and WO 2002/34771. Applicants traverse this rejection.

The Action fails to establish a *prima facie* case of anticipation. At the time of the Action, claim 45 was directed to a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen comprising an amino acid sequence of SEQ ID NO: 364 or an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO:364. The Examiner failed to show that Telford disclosed SEQ ID NO: 364 or an immunogenic fragment of SEQ ID NO: 364 comprising one or more of amino acid sequences 414-420, 427-437, 455-475, 494-510, 386-458, or 458-624 of SEQ ID NO:364. As noted above in regard to the written description rejection, the Examiner appears to be misreading the claims.

Current claim 45 is directed to a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364. Telford also does not disclose the fragments of SEQ ID NO:364 recited in current claim 45. Telford, therefore, does not anticipate the current claims. Applicants respectfully request the withdrawal of this rejection.

#### **E. The Claims Are Novel Over Glaser**

The Action rejects claims 45-49, 53-54, and 61 under 35 U.S.C. § 102(b) as being anticipated by Glaser *et al.* Accession No. ADV88412 and FR 2824074. The Action states that Glaser teaches that pharmaceutical compositions comprising its disclosed peptides are useful in the treatment of *S. agalactiae* infection. Applicants traverse.

Glaser does not anticipate the current claims because Glaser does not teach a pharmaceutical composition comprising an isolated hyperimmune serum-reactive antigen fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364.

Glaser appears to describe an *S. agalactiae* sequencing project. The English abstract indicates that Glaser (FR2824074A1) discloses 2,344 sequences. While Glaser discloses thousands of sequences reportedly obtained from *S. agalactiae*, it does not appear to disclose a single example where even one of these sequences was shown to elicit an immune response in an animal. Furthermore, while Glaser lists a 643 amino acid sequences identified as SEQ ID NO: 806, Glaser does not teach a fragment consisting of an amino acid sequence of 399-417, 503-519, 544-563, 489-556, 386-458, or 458-624 of SEQ ID NO:364.

Glaser has done nothing more than venture a guess that one or more of the thousands of *S. agalactiae* genes that were sequenced and listed in the specification would be useful in a pharmaceutical composition. In order to obtain Applicants' claimed composition from Glaser, a person of ordinary skill in the art would have to analyze an enormous number of *S. agalactiae* sequences and an even larger number of fragments of these sequences. A claim cannot be anticipated by a reference if the allegedly anticipatory disclosure is not enabled. MPEP § 2121.01; *see also* *Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Research*, 304 F.3d 1221, 1228 (Fed. Cir. 2002). Glaser's mere ventured guess that one or more of the thousands of *S. agalactiae* genes that were listed in the Glaser specification may be useful in a pharmaceutical composition is clearly not an enabling disclosure of the subject matter of the current claims.

In view of the above, the current claims are not anticipated by Glaser. Applicants, therefore, request the withdrawal of this rejection.

**F. Conclusion**

Applicants believe this paper to be a full and complete response to the Office Action dated August 9, 2007. Should the Examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-5654.

Respectfully submitted,



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Date: November 8, 2007